

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

DEFENSE EXPERT GENERAL REPORT

OF SALIL KHANDWALA, M.D.

Prepared by



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March 2, 2016

I make this report in connection with the cases involved in the Ethicon, Inc., et al. litigation and hold all opinions stated herein to a reasonable degree of medical certainty.

BACKGROUND, TRAINING AND EXPERIENCE

I am board-certified in Obstetrics and Gynecology, with a subspecialty board certification in Female Pelvic Medicine and Reconstructive Surgery. I did my residency in Obstetrics and Gynecology at Greater Baltimore Medical center, Maryland and a subsequent fellowship in Female Pelvic Medicine and Reconstructive Surgery at University of Maryland/Greater Baltimore Medical Center under the tutelage of Dr. Alfred Bent, the first Urogynecologist in United States.

Since that time, I have served as faculty and Assistant Professor at University of Maryland in the department of Urogynecology.

I have also been part of the two robust clinical trial groups in our subspecialty: Urinary Incontinence Treatment Network (UITN) and Pelvic Floor Disorders Network (PFDN) both under the auspices of the National Institute of Health.

I am presently the Director of Female Pelvic Medicine and Reconstructive Surgery at Beaumont Hospital, Dearborn and also a fellowship director for this subspecialty.

I have a large experience with the implantation of mid-urethral mesh slings, having performed over 1000 mid-urethral slings ranging from the retropubic TVT to the single incision mini-slugs. I also have extensive experience in the use of synthetic mesh augmentation to treat pelvic organ

prolapse and have used mesh in over 800 procedures. Additionally, I have managed complications associated with native tissue repairs, sacralcolpopexies, and transvaginal mesh surgeries both that I and other physicians have performed. I have trained others in performing pelvic floor procedures, including treatment for pelvic organ prolapse. I have conducted studies relating to pelvic reconstructive surgery and treatment as the principal investigator, and have participated in studies conducted with others. Some of the studies have specifically related to use of the Prolift in pelvic floor reconstructive surgery and these have been referenced below. Through my training, clinical and surgical experience and my ongoing review of the literature, I am very comfortable treating pelvic organ prolapse using mesh.

Due to my extensive experience with vaginal mesh augmentation procedures, I understand the pros and cons of each type of mesh, the particular risks of complication for each, and how to avoid them. I also understand how best to approach resolution of complications when they do occur, because I have done it in my practice for my own patients and for patients who have been referred to me.

Pelvic organ prolapse: Incidence and Prevalence

Pelvic floor disorders that include pelvic organ prolapse, urinary and fecal incontinence represent a major public health issue in the United States¹.

Women with these disorders suffer emotional and physical distress and the economic impact on the healthcare system is substantial.²

Data from the 2005 -2006 National Health and Nutrition Examination Survey (NHANES)³ found that approximately 24% of adult women have symptoms of at least one pelvic floor disorder. This proportion increased with age: 39% of women aged 60-79 years and 50% of women aged 80 years or older suffered from at least one disorder. Several studies have shown that age is an important risk factor especially given the changing demographics in the United States^{4, 5, 6, 7}

In 2008, there were 38.6 million American's aged 65 years and older and our elderly population wills more than double to 88.5 million by 2050⁸. Similarly, the 85 and older segment of the population will triple from 5.4 million to 19 million between 2008 and 2050. In addition, amongst those 65 years and older, women greatly outnumber men⁹.

The number of women with pelvic organ prolapse will increase 46% from 3.3 to 4.9 million from 2010-2050. Based on these estimates, nearly 44 million women will suffer from at least one pelvic floor disorder by 2050.

Demographic projections indicate that the public health burden of pelvic organ prolapse will increase considerably over the next several decades such that by a 2030 up to 7 million women may require surgery¹⁰.

In fact, pelvic organ prolapse affects 50% of parous women over 50 years of age, with a lifetime prevalence risk of 30 to 50%¹¹.

Problems with Native Tissue repairs and hysterectomy for management of genital organ prolapse

It is estimated that 11% of all women in the Western world will undergo surgery for prolapse in their lifetime and 30% of these will undergo an operation for recurrent prolapse and the time interval between repeat procedures decreases with each successive repair¹².

Scarring and sclerosis produced by classical pelvic reconstructive surgery can restore only 50% of the pre-operative tissue strength. According to the prospective study of Whiteside et al.¹³, 58% of the women who had undergone surgery for genital prolapse, had a recurrent prolapse at 1-year follow-up evaluation. Age >60 years and pre-operative POP quantification stage 3 or 4 were associated with a greater likelihood of recurrent prolapse at 1 year.

Weber et al¹⁴ reported objective recurrence of anterior compartment prolapse in up to 56% of women following the midline application.

Similarly a prospective randomized controlled trial identified anatomic failures after anterior colporrhaphy in 43% of cases¹⁵.

According to the prospective epidemiologic evaluation of Clark et al¹⁶, 60% of recurrence occurred at the same anatomic site, implying direct failure of the surgical procedure and 40% of recurrence occurred at a different site, which suggests a change in stability of the pelvic floor after surgery.

Hysterectomy and genital organ prolapse

Prolapse is the most common indication for hysterectomy in women aged 55 years and older¹⁷.

Hysterectomy at the time of pelvic organ prolapse repair is a standard practice in most parts of the world despite the fact that descent of the uterus may be consequence not the cause of pelvic organ prolapse. Surprisingly, given its widespread use, concomitant hysterectomy is not an evidence-based practice¹⁸.

Increasingly, women wish to avoid hysterectomy at the time of pelvic organ prolapse repairs because of factors such as desire for future fertility, the belief that the uterus is important for sexual satisfaction, and the success of recent conservative procedures for uterine bleeding and fibroids¹⁸. Moreover, doing a hysterectomy for gynecologic indications increases the risk of subsequent vaginal prolapse.

By the age of 60, nearly 1 in 3 US women will have undergone a hysterectomy¹⁹, of which 90% are performed for benign indications.²⁰

Vaginal hysterectomy has a higher rate of subsequent pelvic organ prolapse surgery compared with other modes of hysterectomy. One may speculate that women undergoing vaginal hysterectomy usually have vaginal laxity. However, subtotal hysterectomy did not provide any protection effects on pelvic floor support compared with total abdominal hysterectomy.

The risk for pelvic organ prolapse surgery was at its highest within 5 years of hysterectomy.

In concurrence with findings from the women's health initiative²¹, Altman et al²² found that each additional childbirth significantly influenced the risks for prolapse surgery as in the ascending gradient, compared with having only one child. Hysterectomized women with only one vaginal childbirth prior to that hysterectomy had a 1.6 times increase risk for prolapse surgery, whereas women with at least 4 vaginal childbirths undergoing a hysterectomy had a nearly 8 fold risk increase for subsequent prolapse surgery.

In conclusion the study by Altman et al²² showed that hysterectomy is associated with an increased risk for pelvic organ prolapse surgery. The risk was most evident within 5 years of surgery in women following a vaginal hysterectomy and in multiparous women. Thus prolapse surgeries that avoid a hysterectomy are likely to not only have a greater success but also avoid possible complications of a hysterectomy procedure.

Vaginal mesh augmentation

With the high recurrence rates especially with large prolapses, operations combining higher rates of first-time success with an attractive safety profile could potentially benefit a large and increasing population of women seeking care.

The notion of reinforcing the pelvic floor defects using biomaterials is not an exclusively contemporary idea²³.

The first data on the efficacy and safety of the transvaginal Prolift mesh reconstruction surgery was reported by the French TVM (total vaginal mesh group)²⁴.

The success rate of 95% for restoration of level 1 support of the apex using a vaginal mesh described by Milani et al²⁵ is compatible with the 74 to 100% success rate of apical support and abdominal sacro-colpopexy^{26, 27} and 89 to 97% success rate for restoration of apical support by sacrospinous ligament fixation²⁸.

The advantage of this total vaginal mesh procedure however is that it adds support to both vaginal compartments as well and compared to the abdominal sacrocolpopexy has a shorter operative time and can be considered as relatively minimally invasive treatment²⁵.

A large French series reported experienced a very low incidence of bladder or rectal injuries percentages of 0.7 and 0.15 respectively²⁹.

Several randomized clinical trials have been performed comparing vaginal mesh augmentation to native tissue repairs.

In 2007, Hiltunen et al³⁰ randomized 201 postmenopausal women with anterior prolapse alone to anterior colporrhaphy with (n = 104) or without (n = 97) surgeon-tailored, low-weight polypropylene mesh (Parietex, Sofradim. Recurrence of disease, defined as prolapse stage II POP-Q, occurred in 38.5% of the nonmesh group and 6.7% of the mesh group ($P < .001$) at 1-year follow-up. There were no significant differences between mesh and nonmesh groups in regards to subjective outcomes, such as pelvic pressure or vaginal bulge.

In another study, Sivaslioglu et al³¹ randomized women with cystoceles to either transvaginal mesh repair (n = 43) or colporrhaphy (n = 42), and determined the cure rates as defined as prolapse \leq stage I POP-Q. Patients with concomitant SUI were excluded. At 1-year follow-up, anatomic cure was achieved in 91% of the mesh group vs 72% of the nonmesh group ($P < .05$). There was no significant difference between groups overall in a postoperative quality-of-life questionnaire (P-QoL). However, when the questionnaire was broken down into individual symptom complexes, the mesh group had significantly less abnormal emptying, frequency, urgency, and pelvic pain, and the nonmesh group reported improved symptoms in abnormal emptying and urgency parameters only.

Nguyen et al³² randomized 74 women with anterior prolapse to either colporrhaphy (n = 37) or transvaginal polypropylene mesh repair (n = 37; Perigee, AMS). The mesh group had a significantly higher optimal or satisfactory pelvic support at 1 year, defined as prolapse \leq stage I POP-Q compared with the traditional repair group (87% vs 55%, $P = .005$).

In a multicenter RCT with the longest follow-up period published to date, Nieminen et al³³ randomized 105 women to surgeon-tailored transvaginal mesh and 97 women to traditional colporrhaphy for anterior wall prolapse. At 3 years follow up, the authors reported recurrence of prolapse \geq stage II POP-Q to be 13% in the mesh group vs 41% in the traditional repair group ($P < .0001$). Although the proportion of postoperative recurrence of symptomatic bulging sensation was similar in each group (65% for nonmesh group vs 69% in mesh group), there was a

significant difference favoring the mesh group if optimal outcome was defined as absence of anatomic recurrence and lack of vaginal bulge sensation (82% vs 55%, $P < .0001$).

In the largest multicenter RCT comparing traditional repair with a commercialized mesh kit (Gynecare Prolift, Ethicon), Altman et al³⁴ randomized women with cystoceles to either anterior colporrhaphy ($n = 182$) or trocar-guided, transvaginal polypropylene mesh repair ($n = 186$). The primary outcome at 1-year follow-up was defined in terms of anatomic success (POP-Q \leq stage I) plus subjective success (absence of a vaginal bulging sensation) and was found in 60.8% of the mesh group but in only 34.5% of the nonmesh group ($P < .001$). Furthermore, the mesh group had significantly less vaginal bulge symptoms at 1 year compared with the colporrhaphy group (75.4% vs 62.1%, $P = .008$).

In another study, Vollegregt et al³⁵ found a 91% anatomic cure rate at 1-year follow-up in 58 women undergoing trocar-guided transvaginal mesh repair (Avaulta, Bard) compared with 41% cure rate in 56 women who had a traditional procedure for cystocele repair ($P < .001$).

Overall, most trials report better anatomic success rates in the mesh-based procedures especially when it concerns the anterior compartment.

As regards the posterior compartment, mesh augmentation has typically not been shown to be of added benefit to colporrhaphy. However, the main reason to put the mesh in the posterior compartment is to help with apical support to the sacrospinous ligaments especially as it pertains to uterine support or hysteropexy.

Summarizing the 2011 Cochrane review, Maher et al⁴¹ report that no definitive conclusions can be drawn about mesh use for posterior or apical vaginal repair. Regarding anterior wall prolapse, however, anterior colporrhaphy had higher rates of objective failure in the same compartment compared with polypropylene mesh onlay (RR 2.14, CI 1.23- 3.74) and surgeon-tailored or commercial transobturator mesh kits (RR 3.55).

Abdominal sacrocolpopexy has greater morbidity, higher cost than vaginal sacrospinous ligament suspension. Moreover, the risk of developing de novo stress urinary incontinence after abdominal repair of anterior and apical defects is 45% at 3 months post procedure³⁶.

Properties of the Prolift and Prolift+M systems

The Prolift™ system or the Gynemesh PS is a Type I monofilament macroporous mesh with pore size >75 µm. The larger pores allows for greater immune surveillance because the larger pore size does not inhibit the migration of the host's immune cells through the mesh³⁷. Prolift has a weight of 43 gm/ m² with a pore size of 2.4 mm. It is a durable mesh that attaches to the anchor muscles and is interposed between the vaginal and the bladder anteriorly and the vagina and the rectum posteriorly.

Prolift+M™ (Ethicon Inc, Somerville, NJ) is a 50-50 blend mesh that contains poliglecaprone-25 knitted with polypropylene. The poliglecaprone-25 (Monocryl™) is absorbed after 3 months, leaving a lower burden of mesh in the vagina, decreasing from 57 g/m² to 31 g/ m². The pore size following absorption increases from 2.5mm to 3.5mm. Preclinical studies have surmised that the

greater distance between pores leads to a compliant and flexible scar tissue that mimics natural tissue mobility³⁸

After the absorption of polyglycaprone-25, the lateral stiffness of the mesh is maintained however, the longitudinal stiffness decreases allowing for the expansion of the neighboring viscera and hence potentially decreasing the potential risk of dyspareunia.

Milani et al²⁵ reported only a 1.6% incidence of mesh stiffness at 1 year with the Prolift+M mesh.

Our experience with the Prolift and Prolift+M system for the management of genital organ prolapse

We have an extensive experience with vaginal mesh and vaginal augmentation surgery for both prolapse and urinary incontinence. I have been performing mesh prolapse cases since 1997 when the abdominal sacrocolpopexy was the predominant route.

Since 2003, I have been using vaginal augmentation surgery for prolapse especially as I had experienced significant personal failures and recurrences with traditional native tissue repairs. I initially started with the IVS tunneller and then the Prolift system.

We performed a retrospective study of 315 cases of Prolift surgery from the time period June 2005 to March 2009. There were a total of 21 (6.6%) failures of which 7 (2.2%) patients were same compartment. The mean blood loss for all patients (n=315) was 106.7 ml There were 3 cases of postoperative hematomas. 2 were asymptomatic and detected at the postoperative 2 week visit. The third patient however, presented with bleeding 10 days postoperatively.

The incidence of mesh exposure in this series was 6.6% (n=21). Our primary outcome analysis of anatomic success was 93.4% overall and 97.8% for the treated compartment.

Due to the properties of the Prolift+M mesh system, we then transitioned to this and had been doing Prolift+M vaginal mesh augmentation surgery from 2009 onwards.

We performed a prospective study⁴² in 157 consecutive subjects who underwent Prolift+M transvaginal mesh surgery from April 2009 to November 2010.

Our composite success score based on prolapse correction and patient satisfaction was 88.1%. Pure anatomic POP-Q stage lower than stage II success that was noted in 94.0%

There was a significant improvement in all the parameters and subscores of the prolapse validated questionnaires (PFDI-20) in the postoperative period compared with the preoperative period.

There were no surgical complications beyond Dindo scale grade I. There were no visceral injuries. Cystourethroscopy was performed in all eligible 122 subjects, and the result was normal without any injuries. The average hospital stay was 1.2 days; essentially overnight.

Three subjects (1.9%) had blood loss greater than 500 mL, with the mean blood loss being 106.1 ml. No subjects required blood transfusion. There were no cases of postoperative hematoma.

Three (2.2%) of 134 subjects had mesh exposure in the vagina lower than the 8% to 15% quoted in the literature^{43, 44}. One subject underwent excision in the operating room, and 2 subjects were managed expectantly. The mesh exposures ranged from 1 to 10 mm. There were no new mesh exposures identified at the 1-year visit.

There were no cases of mesh erosions into the urethra, bladder, or the rectum.

De novo dyspareunia was noted in 3 (6%) of 50 subjects. The typically quoted dyspareunia rate for mesh prolapse surgeries has been between 14.5 -36.1%^{45, 46, 57}.

This low incidence could be due to the properties of the Prolift+M mesh and the warp knitting that allows increased unidirectional elasticity and reduced fibrotic reaction that may benefit vaginal distention during intercourse⁴⁷. Milani et al⁴⁷ also reported a dyspareunia rate of only 2% with the Prolift+M. As discussed later, the overall data shows comparable rates with Prolift and Prolift+M.

Vaginal mesh hysteropexy study⁵¹

Up to 40% of women undergoing hysterectomy subsequently present with vaginal vault prolapse^{48, 49}. In some individuals, removal of the uterus negatively influences sexual and personal identity⁵⁰.

Vaginal mesh hysteropexy was performed at our center in 77 subjects⁵¹ who met the inclusion criteria from the time period 11/06/2008 to 02/23/2011. The mean follow up was 13.7 ± 4.1 (10 to 31 months) months.

Patients were considered to be failures if there was stage II or worse uterine prolapse or they complained of a perceptible vaginal bulge or if they required additional intervention. Our composite success score was 85.7%. The anatomic success, postoperative POP-Q Stage \leq II was noted in 90.9% patients.

This is in contrast to native tissue repairs where Lin et al⁵² reported a recurrence rate of 75% for stage III or IV prolapse and also found that ALL subjects with a preoperative prolapse stage IV had recurrent apical prolapse after a sacrospinous hysteropexy. Based on their data, they advise against performing a sacrospinous non mesh hysteropexy in case of a stage III or IV uterine descent. In our study, with an overall success score of 85.7%, more patients with larger prolapse (stage IV) were successes than failures.

Large series of Prolift+M⁵³

We performed a retrospective study⁵³ in the first 250 consecutive cases of pelvic organ prolapse managed with the Prolift+M mesh system from September 2008 to November 2010.

Our composite success score was 89.2%. Pure anatomic success based upon POP-Q <stage II was 94.1%. Mean intra-operative blood loss was 109.28 ml.

Mesh exposure was noted in 5.4% (12/222) of the cases. Of these patients, 3 (25%) underwent excision of the exposed mesh, two in the operating room and one in the office. The other 9 patients (75%) were managed expectantly. The mean area of exposure was 1.5 cm.

There were no erosions into the neighboring organs such as the bladder or the bowel. There were no visceral injuries or mesh erosions.

The incidence of de novo dyspareunia was 15.8%. This is similar to the dyspareunia rate following traditional prolapse repair (14.5-36.1%) as well as Prolift.

Thus as can be seen with experienced surgeons who do a large number of cases the risk of complications are very low.

Maher et al⁴¹ stated that there are no significant differences in the incidence of other postoperative complications, such as de novo SUI or dyspareunia, compared with traditional repair.

Increasing surgical experience leads to improved outcomes in any field, and this has been observed in the arena of mesh-based repairs⁴⁴

Though the FDA warning places some emphasis on the risk of pelvic pain and mesh contraction following mesh repair, there does not seem to be scientific data in this regard. In the randomized trials reported in this review, there was not a significant increase in pelvic pain in patients who had anterior prolapse repair with mesh compared to the non-meshed patients^{45, 46}. In fact, in some of the reported series, the patients with mesh had less pelvic pain or dyspareunia than the patients

without mesh⁴⁶. Furthermore, ultrasound studies⁵⁶ and studies looking at vaginal length after mesh prolapse repair do not show mesh contraction or loss in vaginal length.

The 2016 Cochrane review summarized by Maher et al⁴⁰ which included additional randomized trials are consistent with the above and showed no significant differences in the incidence of de novo dyspareunia with permanent (polypropylene) mesh compared to traditional repair. Maher et al also reported that compared to traditional repair, lower rates of awareness of prolapse, reoperation for prolapse, and recurrent prolapse on examination were observed with mesh surgery. There was no significant difference in rates of repeat surgery of continence. 8% required surgery to treat mesh exposure. Similarly, Dietz and Maher³⁹ reported that there were no significant differences in de novo dyspareunia, post-operative dyspareunia or PISQ scores compared to traditional repair.

In my opinion, the data do not show a significant difference in pelvic pain, de novo or post-operative dyspareunia, or change in sexual function as assessed by validated questionnaires for Prolift compared to traditional repair. A recent large cohort study⁵⁸ of 250 patients treated with Prolift+M reported that rates of reintervention were low and comparable to rates reported by the authors previously in a large cohort⁵⁹ of 524 Prolift patients. Taking into consideration the difference in follow-up durations (median follow-up 20 months in the Prolift + M group versus 38 months in the Prolift group), there was no statistical difference between the two groups for global rate of reinterventions for exposure, SUI or prolapse recurrence.)

Vaginal mesh prolapse surgery is clearly a complex surgery and should be performed exclusively by surgeons who are experienced in this.

Overall, in my opinion, the data on Prolift and Prolift+M show them to be safe and effective. I strongly believe that vaginal mesh augmentation surgery has an important role in the management of genital organ prolapse especially if it could also help with uterine preservation. The experience of the surgeon, the correct patient indication, correct patient type including comorbidities and prior surgeries along with the right indications form the cornerstone for the surgical management. For example, irritative bladder symptoms may be due to the prolapse, however, they may also be independent of it. Hence it is important to correctly recognize the indication for doing the prolapse surgery. Ultimately, it is critical to counsel the patient correctly regarding the benefit-risk profile of the different treatment options as stated by evidence-based studies.

Similar opinions are held by a large group of surgeons who understand the value of vaginal mesh surgery and know its indications, complications and risk/benefit profile. This was very well reviewed⁶⁰ in the statement made to the FDA by a large group of urogynecology surgeons. It was obvious that even though on the face of it, the number of complications (1,503 cases) may have gone up from 2008 to 2011, the actual incidence of complications was low (0.67%) as the denominator or the number of patients implanted with vaginal mesh (225,000) had significantly gone up in the same time period.

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Salil Khandwala

Reliance List

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MDL Wave 1

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<u>Deponent [Date of Deposition]</u>
Brown, Kathryn - 11.13.2013
Klinge, Uwe - 11.14-15.2013
Margolis, Michael - 11.26.2013
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